

EPA Registration Number 88783-3

Material Sent for Data Extraction

Reg # 88783-3

Description: Amended Label

Material(s) Sent to Data Extraction Contractors:

- ☒ New Stamped Label Dated 2/18/14
- ☐ Notification Dated _____
- ☐ New CSF(s) Dated _____
- ☐ Other: _____

Decision #: 483141

Other Action/Comments: _____

Do not file this cover sheet. Please discard after processing.

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Kathryn Montague

Phone: (703)305-0123 Division: RD/PM Team 23

Date: 2/18/14

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Pesticide Programs

Ms. Leanne Pruett
Pyxis Regulatory Consulting, Inc.
4110 136th St., NW
Gig Harbor, WA 98332
Agent for Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

FEB 18 2014

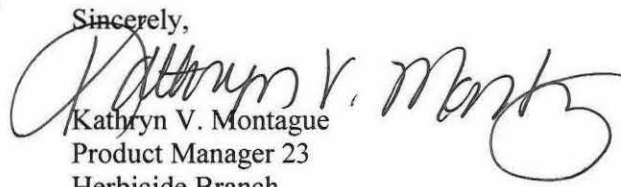
Subject: Label Amendment: Addition of use sites
EPA Reg. No.: 88783-3
Technical Sulfentrazone

Dear Ms. Pruett:

The Agency has received your application for a label amendment, originally dated February 21, 2013, and revised March 18, 2013. The label described above, submitted under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

This labeling supersedes all previous accepted labeling for this product. Please submit one (1) copy of the final printed label before the product is released for shipment. A stamped copy of the accepted label is enclosed for your records. If you have any questions, please contact Kathryn Montague (703-305-1243 or montague.kathryn@epa.gov).

Sincerely,


Kathryn V. Montague
Product Manager 23
Herbicide Branch
Registration Division (7505P)

TECHNICAL SULFENTRAZONE

For Manufacturing of Herbicides

ACTIVE INGREDIENT

Sulfentrazone: N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide

OTHER INGREDIENTS:**TOTAL****% BY WT**

94.0%

6.0%

100.0%

EPA Reg. No. 88783-3

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN

CAUTION

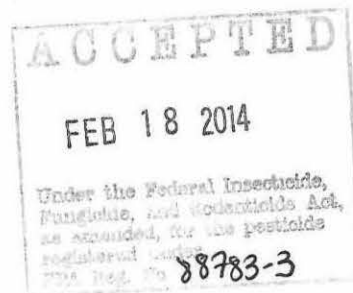
FIRST AID	
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Have person sip a glass of water if able to swallow.• Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Chemtrec at 1-800-424-9300 for emergency medical treatment information 24 hrs. a day.	

Manufactured For:

Summit Agro USA, LLC

8000 Regency Park, Suite 265

Cary, NC 27518

NET CONTENTS: 55.12 lb. (25 kg)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if swallowed, absorbed through skin, or inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only For Formulation into Herbicides Intended For The Following Uses: Asparagus; Berry Crop group 13-07; *Brassica*, head and stem subgroup 5A; *Brassica*, leafy greens subgroup 5B; Cabbage; Citrus Crop Group 10; Dry Bean; Dry Pea; Corn, field, seed, and popcorn; Flax; Horseradish; Melon subgroup 9A; Mint; Vegetable, corm and tuberous subgroup 1C; Vegetable, fruiting subgroup 8-10; Okra; Peanuts; Pea, succulent; Pistachio; Rhubarb; Soybeans; Spring Wheat; Strawberry; Succulent Cowpea; Succulent Lima Bean; Sugarcane; Sunflower Subgroup 20B; Tobacco; Tree Nut Crop Group 14; Terrestrial Non-Crop Use; Tomato (transplanted only); Turf; Turnips; Vegetable Soybean (edamame).

This product may be used to formulate end use products that have specific for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration and for uses for experimental purposes that are in compliance with U.S. EPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal

PESTICIDE STORAGE: Store in original container only. Keep container closed when not in use.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Completely empty liner into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into processing equipment. Then dispose of liner in sanitary landfill or by incineration if allowed by State and local authorities. Offer the drum for recycling if available.

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Summit Agro USA, LLC. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Summit Agro USA, LLC makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Summit Agro USA, LLC, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

[EPA Approval Date]

Montague, Kathryn V.

From: Leanne Pruett [Leanne@PyxisRC.com]
Sent: Tuesday, February 18, 2014 12:05 PM
To: Montague, Kathryn V.
Subject: RE: 88783-3 question on oral first aid statement
Attachments: 088783-3.20140218.Technical Sulfentrazone label_add crop and noncrop uses and update first aid.pdf

Thanks, Kay -

Here it is!

Best,
Leanne

-----Original Message-----

From: Montague, Kathryn V. [<mailto:Montague.Kathryn@epa.gov>]
Sent: Tuesday, February 18, 2014 12:00 PM
To: Leanne Pruett
Subject: RE: 88783-3 question on oral first aid statement

Hi, Leanne,

The only TRB tox review on the original product is essentially a very short memo stating that the product is similar to the cited product, and that the acute toxicity profile and language should be the same for both products. I can send you a copy if you'd like, but there's really not much to it.

If you could go ahead and send me a revised label, changing the "do not give water" statement to "Have person sip a glass of water if able to swallow, " I can go ahead and wrap this amendment up for you (finally!).

Thank you,
Kay

-----Original Message-----

From: Leanne Pruett [<mailto:Leanne@PyxisRC.com>]
Sent: Friday, February 14, 2014 4:38 PM
To: Montague, Kathryn V.
Subject: RE: 88783-3 question on oral first aid statement

Hi, Kay -

We think that the statement 'do not give any liquid to the person' was an oversight, so we have no objection to changing it to 'have person sip a glass of water if able to swallow'

Not sure if they ever caught this in the initial TRB review or not. We don't have a copy of that, and would appreciate one for our files, if you could send it to us.

If you want me to update this on the label and send it to you, let me know and I will do so.

Thanks,
Leanne

-----Original Message-----

From: Leanne Pruett
Sent: Friday, February 14, 2014 4:14 PM
To: 'Montague, Kathryn V.'
Subject: RE: 88783-3 question on oral first aid statement

Hey, Kay -

Thanks for checking on this.

I didn't initially register the product - Ann Tillman did. I see that she me-too'ed FMC's Sulfentrazone Tech, which has the statement that you indicated - "have person sip a glass of water if able to swallow"

I'm just checking with Ann to see if there's any reason she has it as written (do not give any liquid to the person). As soon as I hear from her, I'll follow up with you (I see from her Skype account that she's in the office, so shouldn't be too long.

Best,
Leanne

-----Original Message-----

From: Montague, Kathryn V. [<mailto:Montague.Kathryn@epa.gov>]
Sent: Friday, February 14, 2014 3:12 PM
To: Leanne Pruett
Subject: 88783-3 question on oral first aid statement

Hi, Leanne,

I'm trying to wrap this up from home today. I notice that you have, "Do not give any liquid to the person" in the approved First Aid statement. However, the cited product and your csf appear to support using, "have person sip a glass of water if able to swallow". Was the original statement on your product used intentionally?

Thank you,
Kay

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

Submitted: February 21, 2013
Revised: March 18, 2013

Kathryn Montague (PM23)
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

RE: Summit Agro USA, LLC. – Technical Sulfentrazone (EPA Reg. No. 88783-3)
Label Amendment – addition of use sites

Dear Ms. Montague,

On behalf of Summit Agro USA, LLC, I am submitting an application to amend the registration of Technical Sulfentrazone (EPA Reg. No. 88783-3), to add additional use sites (berry crop group13-07, citrus crop group 10, pistachio, rhubarb, succulent cowpea, sunflower subgroup 20B, terrestrial non-crop uses, tree nuts crop group14, turnips, spring wheat, vegetable soybean (edamame)). These use sites are found on the labels of currently registered manufacturing use and end use products. Since these use sites are found on registered manufacturing and end use product labels, these use sites should be allowed to be added to the Technical Sulfentrazone label¹.

In support of this label amendment, the following documents are enclosed:

1. EPA Application Form 8570-1
2. One (1) copy of Technical Sulfentrazone label with changes tracked
3. Three (3) copies of Technical Sulfentrazone label with changes incorporated
4. One copy of the proposed label on CD
5. Certification with respect to Label Integrity
6. EPA Form 8570-34 (Certification with respect to Citation of Data)
7. EPA Form 8570-35 – Data Matrix – Agency Internal Copy and Public File Copy

¹ The terrestrial non-crop use site is not listed on FMC's Sulfentrazone Technical label (EPA reg. No. 279-3149). However, this use site is approved on the labels for Sulfentrazone 4F ROW Herbicide (EPA Reg. No. 279-3295), F 6285 4F Cal Herbicide (EPA Reg. No. 279-3370), and also on the most recent EPA stamped, accepted label (dated 9/28/12) for Spartan 4F Herbicide (EPA Reg. No. 279-3220). Summit Agro USA, LLC wanted to ensure that its technical label was as comprehensive as possible, despite the apparent oversight of not listing these uses on the Sulfentrazone Technical label. The terrestrial non-crop use site includes: railroad, highway, roadside, pipeline, utility rights of way, industrial areas, fence rows and other listed non-crop sites.

8. Letter of Authorization

Because no data are being submitted with this amendment and no data will need to be reviewed to approve the proposed labeling, Summit believes this action is not subject to a Pesticide Registration Service Fee. If you have any questions or concerns regarding this application for registration, or require additional information, please contact me at (253) 853-7369 or Leanne@PyxisRC.com.

Best Regards,



P. Leanne Pruett
Pyxis Regulatory Consulting

Enclosures

cc: Summit Agro USA, LLC



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 25, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

ROSS GILBERT
PYXIS REGULATORY CONSULTING, INC
SUMMIT AGRO USA, LLC
4110 136TH ST. NW
GIG HARBOR, WA 98332-

MAR 4 2013

PRODUCT NAME: TECHNICAL SULFENTRAZONE
COMPANY NAME: SUMMIT AGRO USA, LLC
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 88783-3
EPA RECEIPT DATE: 02/22/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 23, at (703) 305-1243.

Sincerely,

A handwritten signature in black ink, appearing to be "Sgt".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

February 21, 2013

Kathryn Montague (PM23)
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

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8. Letter of Authorization

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Best Regards,



P. Leanne Pruett
Pyxis Regulatory Consulting

Enclosures

cc: Summit Agro USA, LLC



8000 Regency Park Suite 265 Cary, North Carolina, 27519 919-653-4620

September 1, 2011

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agents for Summit Agro USA, LLC (EPA Company Number pending), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in cursive script that reads "Susan J. Hill".

Susan J Hill

Chief Financial Officer

Summit Agro USA, LLC

cc: Pyxis Regulatory Consulting, Inc.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Summit Agro USA, LLC / 88783-3	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Summit Agro USA, LLC / Technical Sulfentrazone	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Summit Agro USA, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St., NW, Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 279-3149 Product Name Sulfentrazone Technical	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of amended label to add additional use sites (berry crop group 13-07, citrus crop group 10, pistachio, rhubarb, succulent cowpea, sunflower subgroup 20B, terrestrial non-crop uses, tree nuts crop group 14, turnips, spring wheat, vegetable soybean (edamame)). As no data are being submitted with this amendment, nor will data need to be reviewed to approve the proposed labeling, Summit Agro USA, LLC believes this action is not subject to a Pesticide Registration Service Fee.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify)	PE lined fiber-board drums
* Certification must be submitted					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55 lb / 22 kg		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name P. Leanne Pruett		Title Agent	
		Telephone No. (Include Area Code) 253-853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name P. Leanne Pruett		5. Date February 21, 2013	

TECHNICAL SULFENTRAZONE **For Manufacturing of Herbicides**

ACTIVE INGREDIENT

Sulfentrazone: N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide

OTHER INGREDIENTS:

TOTAL

% BY WT

94.0%

6.0%

100.0%

EPA Reg. No. 88783-3

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN **CAUTION**

FIRST AID	
If inhaled:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give any liquid to the person. • Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Chemtrec at 1-800-424-9300 for emergency medical treatment information 24 hrs. a day.	

Manufactured For:

Summit Agro USA, LLC
 8000 Regency Park, Suite 265
 Cary, NC 27518

NET CONTENTS: 55.12 lb. (25 kg)

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Do not contaminate water, food, or feed by storage or disposal

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LIMITATION OF WARRANTY AND LIABILITY

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DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Summit Agro USA, LLC makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Summit Agro USA, LLC, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

[EPA Approval Date]



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number (253) 853-7369 Summit Agro USA, LLC c/o Pyxis Reg. Consulting, 4110 136th St., NW, Gig Harbor, WA 98332	EPA Registration Number/File Symbol 88783-3
Active Ingredient(s) and/or representative test compound(s) Sulfentrazone	Date February 21, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food, Terrestrial Feed, Terrestrial Non-Food	Product Name Technical Sulfentrazone

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

2-21-2013

Typed or Printed Name and Title

P. Leanne Pruett, Agent

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date February 21, 2013			EPA Reg. No./File Symbol 88783-3		Page 1 of 5
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518			Product Technical Sulfentrazone		
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	48890701	Summit Agro USA, LLC	OWN	
830.1600	Description of Materials Used to Produce the Product	48890701	Summit Agro USA, LLC	OWN	
830.1620	Description of Production Process	48890701	Summit Agro USA, LLC	OWN	
830.1650	Description of Formulation Process				Not required ¹
830.1670	Discussion of Formation of Impurities	48890701	Summit Agro USA, LLC	OWN	
830.1700	Preliminary Analysis	48890702	Summit Agro USA, LLC	OWN	
830.1750	Certified Limits	48890701	Summit Agro USA, LLC	OWN	
830.1800	Enforcement Analytical Method	48890702 48890703	Summit Agro USA, LLC Summit Agro USA, LLC	OWN OWN	
830.6302	Color	48890704	Summit Agro USA, LLC	OWN	
830.6303	Physical State	48890704	Summit Agro USA, LLC	OWN	
830.6304	Odor	48890704	Summit Agro USA, LLC	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	48890704	Summit Agro USA, LLC	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility	48890704	Summit Agro USA, LLC	OWN	
830.6315	Flammability	48890705	Summit Agro USA, LLC	OWN	Waiver ²
Signature 			Name and Title P. Leanne Pruett, Consultant		Date Feb. 21, 2013

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Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518			Product Technical Sulfentrazone		
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explosibility	48890705	Summit Agro USA, LLC	OWN	Waiver ³
830.6317	Storage Stability	48890705	Summit Agro USA, LLC	OWN	PRN 92-5 ⁴
830.6319	Miscibility				Not required ⁵
830.6320	Corrosion Characteristics	48890705	Summit Agro USA, LLC	OWN	PRN 92-5 ⁴
830.6321	Dielectric Breakdown Voltage				Not required ⁶
830.7000	pH	48890704	Summit Agro USA, LLC	OWN	
830.7050	UV/Visible Absorption	48890704	Summit Agro USA, LLC	OWN	
830.7100	Viscosity				Not required ⁷
830.7200	Melting Point/Melting Range	48890704	Summit Agro USA, LLC	OWN	
830.7220	Boiling Point/Boiling Range				Not required ⁸
830.7300	Density/Relative Density/Bulk Density	48890704	Summit Agro USA, LLC	OWN	
830.7370	Dissociation Constants in Water	48890704	Summit Agro USA, LLC	OWN	
830.7520	Particle size, fiber length, diameter distribution	48890705	Summit Agro USA, LLC	OWN	Waiver ⁹
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				See 830.7570
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7570
Signature 			Name and Title P. Leanne Pruett, Consultant		Date Feb. 21, 2013

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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography	48890704	Summit Agro USA, LLC	OWN	
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	48890704	Summit Agro USA, LLC	OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	48890704	Summit Agro USA, LLC	PL	
870.1100 (81-1)	Acute Oral Toxicity: Rat	Cite-All	Summit Agro USA, LLC	PAY	
870.1200 (81-2)	Acute Dermal Toxicity: Rat	Cite-All	Summit Agro USA, LLC	PAY	
870.1300 (81-3)	Acute Inhalation Toxicity: Rat	Cite-All	Summit Agro USA, LLC	PAY	
870.2400 (81-4)	Primary Eye Irritation: Rabbit	Cite-All	Summit Agro USA, LLC	PAY	
870.2500 (81-5)	Primary Dermal Irritation	Cite-All	Summit Agro USA, LLC	PAY	
870.2600 (81-6)	Dermal Sensitization	Cite-All	Summit Agro USA, LLC	PAY	
Signature 			Name and Title P. Leanne Pruett, Consultant		Date Feb. 21, 2013

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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific and Generic Data Requirements					
Summit Agro USA, LLC is using the cite-all option to satisfy product specific and generic data requirements. Summit Agro USA, LLC will make offers-to-pay to the following companies on the September 27, 2012 Data Submitters List for sulfentrazone.					
		Cite-All	FMC Corp. Agricultural Products Group	PAY	
		Cite-All	E. I. DuPont de Nemours and Co., Inc.	PAY	
		Cite-All	PBI/Gordon Corp.	PAY	
		Cite-All	Chemsico	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	Agricultural Reentry TF	PAY	
		Cite-All	FIFRA Endangered Species Task Force LLC	PAY	
		Cite-All	Agricultural Handlers Exposure TF	PAY	
		Cite-All	Summit Agro North America Holding Corporation	PAY	
Signature 			Name and Title P. Leanne Pruett, Consultant		Date Feb. 21, 2013

Endnotes for Data Matrix for Technical Sulfentrazone
Dated February 21, 2013


Page 5 of 5

-
- ¹ **830.1650** - These data are not required for the registration of a manufacturing use product. See 830.1620 for production process information.
- ² **830.6315** - Summit Agro USA, LLC requests a waiver from this data requirement because Technical Sulfentrazone is a solid and is not expected to be flammable.
- ³ **830.6316** - Summit Agro USA, LLC requests a waiver from this data requirement because sulfentrazone does not have the chemical bonds or functional groups associated with explosive chemicals.
- ⁴ **830.6317, 830.6320** - Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Summit Agro USA, LLC will conduct these studies if requested by the Agency.
- ⁵ **830.6319** - This data requirement is required when the MUP is an emulsifiable liquid and to be diluted with petroleum solvents. Technical Sulfentrazone is a technical material that is a solid and is not to be diluted with petroleum solvents. This data requirement is not applicable to Technical Sulfentrazone.
- ⁶ **830.6321** - These data are not required unless the product is an end-use product. Technical Sulfentrazone is a technical grade material and this data requirement is not applicable.
- ⁷ **830.7100** - This requirement is not applicable to Technical Sulfentrazone because it is a solid.
- ⁸ **830.7220** - This requirement is not applicable to Technical Sulfentrazone because it is a solid. The melting point of Technical Sulfentrazone was determined and that data is presented Volume 3 of this submission.
- ⁹ **830.7520** - A waiver is requested by Summit Agro USA, LLC for this data requirement for Technical Sulfentrazone because it is not a fibrous material and is not a water-insoluble material.

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DATA MATRIX

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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
					Not required ¹
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Signature 		Name and Title P. Leanne Pruett, Consultant

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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Summit Agro USA, LLC	OWN	Waiver ³
			Summit Agro USA, LLC	OWN	PRN 92-5 ⁴
					Not required ⁵
			Summit Agro USA, LLC	OWN	PRN 92-5 ⁴
					Not required ⁶
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
					Not required ⁷
			Summit Agro USA, LLC	OWN	
					Not required ⁸
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	Waiver ⁹
					See 830.7570
		See 830.7570			
Signature 			Name and Title P. Leanne Pruett, Consultant		Date Feb. 21, 2013

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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
					See 830.7840
			Summit Agro USA, LLC	PL	
			Summit Agro USA, LLC	PAY	
			Summit Agro USA, LLC	PAY	
			Summit Agro USA, LLC	PAY	
			Summit Agro USA, LLC	PAY	
			Summit Agro USA, LLC	PAY	
Signature 			Name and Title P. Leanne Pruett, Consultant		Date Feb. 21, 2013

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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			FMC Corp. Agricultural Products Group	PAY	
			E. I. DuPont de Nemours and Co., Inc.	PAY	
			PBI/Gordon Corp.	PAY	
			Chemsico	PAY	
			Spray Drift Task Force	PAY	
			Agricultural Reentry TF	PAY	
			FIFRA Endangered Species Task Force LLC	PAY	
			Agricultural Handlers Exposure Task Force	PAY	
			Summit Agro North America Holding Corporation	PAY	
Signature 			Name and Title P. Leanne Pruett, Consultant		Date Feb. 21, 2013

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
88783-3	February 21, 2013	088783-00008.20130221.TechSulf Iblamd_add uses.PDF

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature

2-21-2013
Date

P. Leanne Pruett

Name (typed)

Agent

Title

Material Sent for Data Extraction

Reg. # 88783-~~4~~3

Description: New Product

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 2/6/13

☐ Notification Dated _____

☒ New CSF(s) Dated 7/12/12

☐ Other: _____

☒ Decision #: 467536

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Beth Benbow

Phone: 347-8072 Division: RD

Date: 2/12/13



U.S. ENVIRONMENTAL PROTECTION
AGENCY

Office of Pesticide Programs
Registration Division (7505P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number:

88783-3

Date of Issuance:

FEB 06 2013

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance: **unconditional**

Name of Pesticide Product:

Technical Sulfentrazone

Name and Address of Registrant (include ZIP Code):

Summit Agro USA, LLC
8000 regency Park, Suite 265
Cary, NC 27518

c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The basic formulation (dated July 12, 2012) is acceptable and will be added to your file.

This product is registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration review/reregistration of your product when the Agency requires all registrants of similar products to submit data.
2. Make the following label revision(s):
 - a. Revise "EPA Reg. No.88783-" to "EPA Reg. No. 88783-3."
 - b. Assure that the EPA establishment number is also added to the final printed label.
3. Within one year of the date on this registration notice, the Storage Stability (830.6317) and Corrosion Characteristics (830.6320) studies must be submitted. They must be conducted in the commercial containers of this product and observations should be made at 0, 3, 6, 9, and 12 month intervals.
4. Per 40 CFR 156.10(6), submit one copy of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec.6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. If you have any questions regarding this notice, please contact Beth Benbow of my staff at benbow.bethany@epa.gov.

Signature of Approving Official:

Kathryn V. Montague
Project Manager 23
Herbicide Branch
Registration Division (7505P)

Date:

FEB 06 2013

TECHNICAL SULFENTRAZONE

For Manufacturing of Herbicides

ACTIVE INGREDIENT

Sulfentrazone: N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide

OTHER INGREDIENTS:**TOTAL****% BY WT**

94.0%

6.0%

100.0%

EPA Reg. No. 88783-

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give any liquid to the person.• Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Chemtrec at 1-800-424-9300 for emergency medical treatment information 24 hrs. a day.	

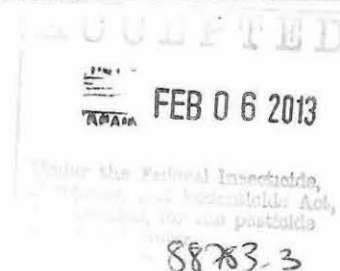
Manufactured For:

Summit Agro USA, LLC

8000 Regency Park, Suite 265

Cary, NC 27518

NET CONTENTS: 55.12 lb. (25 kg)



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if swallowed, absorbed through skin, or inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only For Formulation into Herbicides Intended For The Following Uses: Asparagus; *Brassica*, head and stem subgroup; *Brassica*, leafy greens subgroup; Cabbage; Dry Bean; Dry Pea; Corn, field, seed, and popcorn; Flax; Horseradish; Melon subgroup; Mint; Vegetable, corn and tuberous subgroup; Vegetable, fruiting subgroup; Okra; Peanuts; Pea, succulent; Soybeans; Strawberry; Succulent Lima Bean; Sugarcane; Sunflower; Tobacco; Tomato (transplanted only); Turf.

This product may be used to formulate end use products that have specific for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration and for uses for experimental purposes that are in compliance with U.S. EPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal

PESTICIDE STORAGE: Store in original container only. Keep container closed when not in use.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Completely empty liner into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into processing equipment. Then dispose of liner in sanitary landfill or by incineration if allowed by State and local authorities. Offer the drum for recycling if available.

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Summit Agro USA, LLC. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Summit Agro USA, LLC makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Summit Agro USA, LLC, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

[draft 20120717]

NOTE FOR RECORD

EPA Reg. No./ File Symbol: **88783-G**

Product Name: **Technical Sulfentrazone**

Application Dated: **7/17/2012**

PRIA Due Date: **2/10/13**

Action Description: **Summit Agro USA, LLC would like to register a technical product consisting of 94% sulfentrazone. (solid-powder)**

Comments:

PRODUCT CHEMISTRY:

Submitted MRID 488907-01-05 found acceptable to support group A and B prod. chem. with the exception of storage stability and corrosion characteristics.

Submitted a Basic CSF dated 7/12/2012: found acceptable by TRB (see MEMO dated 1/22/13 in file).

ACUTE TOXICITY REVIEW:

-Signal Word: CAUTION

-Claimed Cite-ALL

-TRB TOX was asked to consider the new impurities as well. Since the impurities were not of tox. concern (pg. 47 MRID 488907-01), the tox. profile for this product matches that of the currently registered FMC technical (279-3149).

- HASPOC memo on inhalation dated 3/2/12 cites cat III (caution) for acute exposures

DATA COMPENSATION:

Submitted own product chemistry

CITE-ALL for acute tox and generic data- made an offer to pay

LABEL REVIEW:

No revisions needed

DATA GAPS:

Storage Stability (830.6317)

Corrosion Characteristics (830.6320)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

March 2, 2012
TXR # 0050684

SUBJECT: **Sulfentrazone:** Summary of Hazard and Science Policy Council (HASPOC) Meeting of February 16, 2012: Recommendations on the need for a 28-day inhalation study.

PC Code: 129081
Decision No.: *NA*
Petition No.: N/A
Risk Assessment Type: Single Chemical/
Aggregate
TXR No.: 0050684
MRID No.: NA

DP Barcode: *NA*
Registration No.: *NA*
Regulatory Action: Section 3
Case No.: N/A

CAS No.: 122836-35-5
40 CFR: §180.515

FROM: Deborah Smegal, MPH
Executive Secretary, HASPOC
Health Effects Division (7509P)

Deborah C Smegal

TO: Chester Rodriguez, Ph.D., Toxicologist
Dana Vogel, Branch Chief
Risk Assessment Branch 1 (RAB1)
Health Effects Division (HED; 7509P)

THROUGH: Jess Rowland, Co-Chair *Jess Rowland*
Anna Lowit, Ph.D, Co-Chair
HASPOC
Health Effects Division (7509P)

MEETING ATTENDEES:

HASPOC Members: Jonathan Chen, Jeff Evans, Ray Kent, Anna Lowit, Mike Metzger, Elissa Reaves, Jess Rowland, Jessica Ryman, PV Shah, Debbie Smegal

Presenter: Chester Rodriguez

Other Attendees: Myron Ottley, Kristin Rury, Anwar Dunbar, Kelly Lowe, Julie Van Alstine

I. PURPOSE OF MEETING:

FMC Corporation has proposed a Section 3 Registration (PP# 1F7838) for application of sulfentrazone on several agricultural crops. Based on its registered use pattern, a handler will likely be exposed repeatedly to aerosolized sulfentrazone. In the current risk assessment, an oral study is used for assessing risk via the inhalation route of exposure. On February 16, 2012, the Hazard Science Policy Council (HASPOC) evaluated the need for a 28-day inhalation study in rats.

II. SUMMARY OF USE PROFILE & PREVIOUS RISK ASSESSMENT:

Sulfentrazone is a soil-applied herbicide used for the control of susceptible broadleaf, grass and sedge weeds. FMC Corporation has proposed a Section 3 registration (Petition# 1F7838) for application of sulfentrazone on the following agricultural crops: citrus fruit crop group 10-10, low growing berry crop group 13-07, tree nut crop group 14 and pistachios, and crop group 18: nongrass animal feeds. Sulfentrazone is currently registered for use on a number of agricultural crops, ornamental turf/plant products, residential lawns, and non-crop land areas. The most recent HED human-health risk assessment for sulfentrazone was conducted in 2010 (Memo, 08/11/10, M. Lowe *et al.*, D364882).

The proposed products include both liquid and dry flowable formulations. Sulfentrazone may be used by residential homeowners as well as occupational handlers. Sulfentrazone may be applied to registered use sites with handheld, ground, chemigation or aerial equipment or impregnated onto dry bulk fertilizer. For both residential and occupational exposure, the durations of exposure are expected to be short-term (1-30 days). The level of concern (LOC) for risk estimates is a margin of exposure (MOE) of less than 100 for short- and intermediate-term exposure.

Sulfentrazone belongs to a class of herbicides that inhibit protoporphyrinogen oxidase (PPO) in target organisms, ultimately resulting in disruption of chlorophyll biosynthesis. In mammals, PPO is also an important enzyme in heme biosynthesis and its inhibition can lead to toxic effects associated with disruption of heme utilization (e.g., red blood cells). Some of the toxicities reported for sulfentrazone in mammals are consistent with inhibition of PPO. Sulfentrazone is a developmental toxicant via the oral and dermal routes of exposure. Developmental effects in rats and rabbits consisted of reductions in the number of implantations (rats only), increase in early resorptions (rats and rabbits), reduction in live fetuses per litter (rats and rabbits), delayed skeletal ossifications (rats) and decreased fetal body weights (rats). In the 2-generation rat reproductive toxicity study, developmental effects included an increased duration of gestation, reduced prenatal viability (fetal and litter), reduced litter size, an increased number of stillborn pups, pup body weight deficits along with reduced pup and litter postnatal survival.

In the most recent risk assessment, an oral Point of Departure (POD) was used for assessing risks via inhalation exposure from occupational and residential uses. The POD for short and

intermediate term exposures is a no observed adverse effect level (NOAEL) of 10 mg/kg/day for developmental toxicity (decreased fetal weights, and retarded skeletal development) at 25 mg/kg/day (LOAEL) in the rat developmental study. A MOE of 100 is adequate for both exposure scenarios.

All residential and occupational inhalation MOEs are greater than the LOC of 100 based on a POD extrapolated from an oral study. For residential uses, mixing/loading/applying dry flowables with backpack applications resulted in the lowest MOE of 7600. For workers, mixing and loading for a high acreage aerial application of dry flowables resulted in the highest inhalation exposure and lowest MOEs of 200.

III. STUDY WAIVER REQUESTS

Inhalation Study

In the past, OPP used a set of criteria when considering the scientific information available to waive (or not waive) an inhalation study. These criteria included: (1) the severe irritation and corrosivity of the chemical; 2) the volatility of the chemical; 3) the aerosol particle size; 4) the acute toxicity category of the chemical; and (5) the extrapolated inhalation MOEs (i.e., how much higher are the MOEs than the level of concern). In 2009, OPP brought this issue to the Scientific Advisory Panel and developed an issue paper on risk assessment approaches for semi-volatile pesticides. As part of that paper, an analytical comparison was conducted of oral and inhalation experimental toxicology studies. In general, this analysis showed variation in the degree to which oral PODs were protective of potential inhalation toxicity. In many cases, the oral POD was protective, but in some cases the inhalation PODs were significantly more sensitive. Currently, OPP uses a weight of the evidence (WOE) approach discussed below which builds upon experience using the previously used criteria listed above and informed by the 2009 SAP. As approaches for route to route extrapolation evolve and improve in the future, OPP may, if appropriate, bring additional considerations into the WOE analysis.

Inhalation exposure can be to vapors, droplets, and/or particles/dusts. The form of this exposure is determined by a number of factors, including (1) physical-chemical properties, (2) use pattern, and (3) exposure scenario. The interim WOE approach considers:

1. **Physical-chemical properties:** Vapor pressure and Henry's law constant are key considerations with respect to the volatilization after sprays have settled. Sulfentrazone has a low vapor pressure (8×10^{-10} mm Hg (25°C)). The Henry's law constant at 20°C is 2.65×10^{-11} atm-m³/mol. However, low vapor pressure and/or Henry's law constant does not preclude exposure to aerosolized droplets or particles/dusts.
2. **Use pattern & exposure scenarios:** Any application scenario that leads to inhalation exposure to droplets needs to be considered in the WOE analysis for an inhalation toxicology study waiver request. Airblast and aerial applications are more likely to lead to higher occupational handler inhalation exposure, particularly to droplets; and may also

contribute to spray drift. In the case of sulfentrazone, mixer/loaders for aerial occupational applications resulted in the highest inhalation exposure (MOE = 200). For residential uses, mixing/loading/applying with backpack applications resulted in the lowest MOE of 7600.

3. **Margins of Exposure (MOEs):** The MOE estimates for inhalation scenarios were calculated using an oral toxicity study and should be considered in the WOE analysis for an inhalation toxicology study waiver request. In the past, OPP has used MOEs of approximately 10 times higher than the level of concern as a benchmark for granting waiver requests. The 2009 analysis suggests this approach is appropriate for most pesticides, but not all. Under the interim WOE approach, MOEs from 10-100 times greater than the level of concern will be considered in combination with other factors discussed here. Mixing and loading dry flowable sulfentrazone for aerial application to cotton results in the highest exposure and an MOE of 200.
4. **Toxicity:** Sulfentrazone was classified as Category III for acute inhalation toxicity in the rat. There were no deaths reported. However, there were clinical signs reported post-exposure through day 1 including decreased locomotion, lacrimation/chromodacryorrhea, nasal discharge, and rales. Sulfentrazone was classified as Category III because chamber concentration failed to reach the required values > 5 mg/L for Category IV.

Following oral administration in the rat, sulfentrazone was well absorbed as indicated by the excretion of nearly all radioactivity in urine by 72 hours post-dosing. There was no indication of accumulation; only the carcass, liver, and bone showed detectable levels of radioactivity (<0.5% of the administered) at 72 hours post-dosing. There were no apparent sex dependent differences in the pharmacokinetic profile.

Sulfentrazone inhibits the enzyme PPO in target plants and the results of subchronic and chronic toxicity studies in mammalian systems are consistent with this mode of action, given that PPO is an important enzyme in the heme synthetic pathway in mammals. Disruption of heme biosynthesis was indicated by signs of anemia [decreases in hematocrit, hemoglobin, and mean cell volume (MCV)] in mice, rats, and dogs at comparable dose levels from short- through long-term exposure without increasing much in severity. Developmental effects in rats were the most sensitive effect in the database, and are the basis of the inhalation PODs.

When considering a waiver request for an inhalation toxicity study, the Agency will evaluate other pesticides which share the same Mode of Action (MOA) and/or are in the same class. These pesticides can provide important information with respect to potential inhalation toxicity. Specifically, if other similar pesticides show inhalation toxicity studies to be more sensitive, an inhalation toxicity study may be required regardless of MOE, depending on the exposure profile.

Sulfentrazone belongs to a class of herbicides that inhibit PPO in target organisms, ultimately resulting in disruption of chlorophyll biosynthesis. In mammals, PPO is also an important enzyme in heme biosynthesis and its inhibition can lead to toxic effects associated with disruption of heme utilization (e.g., red blood cells). Some of the toxicities reported for sulfentrazone in mammals are consistent with inhibition of PPO.

IV. HASPOC RECOMMENDATIONS:

The HASPOC concludes based on a weight of evidence (WOE) approach that a 28-day inhalation toxicity study is required. This approach considered all of the available hazard and exposure information for sulfentrazone, including: (1) the use of an oral POD that results in MOEs as low as 200 (the lowest MOE) for risk via the inhalation route resulting from occupational and residential exposures; (2) the physical/chemical properties and formulation as a dry flowable; (3) the toxicological profile of sulfentrazone and concern for pulmonary effects in the acute inhalation study; and (4) there is repeated inhalation exposure based on the use pattern and method of application (i.e., aerial). The HASPOC further concluded that a 28 day inhalation study would be adequate to assess both short- and intermediate-term exposure scenarios based on the currently registered labels and use pattern.

The HASPOC recommends that the registrant submit an inhalation study protocol for Agency review prior to conducting study to ensure the appropriate aerosol particles are tested, and for guidance on how to achieve adequate air concentrations



FEE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

BARCODE: D404382; FILE SYMBOL No.: 88783-G; PRODUCT: Technical Sulfentrazone

DATE: January 22, 2013

SUBJECT: Product Chemistry Review of "Technical Sulfentrazone" TGAI/MUP

FROM: Shyam Mathur
Product Chemistry Team Leader
Technical Review Branch / Registration Division (7505P)

SB Mathur
01-23-13
JCK

TO: Bethany Benbow / Kathryn Montague, RM 23
Herbicide Branch / Registration Division (7505P)"

DP BARCODE: 404382
DECISION NO.: 467536
REGISTRATION NO./FILE SYMBOL NO.: 88783-G
PRODUCT NAME: Technical Sulfentrazone TGAI/MUP
PC CODE: 129081
REGISTRANT: Summit Agro USA, LLC
USE: Herbicide
FOOD USE: Yes [X] No []
MRID NUMBERS: 488907-01 to 488907-05

INTRODUCTION:

Pyxis Regulatory Consulting Incorporation on behalf of the registrant Summit Agro USA has submitted an application for the registration of the new technical grade product "Technical Sulfentrazone." The sulfentrazone technical is produced by Jiangsu Jiangxi Heyi Chemical Company, Longchen Town, Jiujiang City, Jiangxi, PR China. The registrant has submitted a basic CSF dated July 12, 2012 and the supporting product chemistry data with MRID Nos. 488907-01 through 488907-05 along with the product label. TRB has been asked to determine the acceptability of the proposed basic CSF and the supporting product chemistry data.

SUMMARY OF FINDINGS:

1. The registrant submitted a CSF for basic formulation (dated 07-12-12). The product chemistry data corresponding to guideline reference 830.1550 (product identity & composition) submitted on the CSF satisfy the data requirements of 40CFR§158.320. The data corresponding to guideline reference 830.1750 (certified limits) satisfy the requirements of 40CFR§158.350. The nominal concentration of the AI on the CSF (94%) concurs with the product label claim nominal concentration [MRID No. 488907-01]
2. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.325 [MRID No. 488907-01].

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for sulfentrazone tgai/mup (produced by Jiangsu Jiangxi Heyi Chemical Company, Longchen Town, Jiujiang City, Jiangxi, PR China) and has concluded that:

1. The product chemistry data submitted corresponding to guideline 830 series group A and group B are acceptable.
2. The proposed basic CSF (dated July 7, 2012) is supported by the five batch analysis and is acceptable.
3. Based on the justifications provided, the waiver requests for the following guidelines are acceptable: 830.6315 (flammability), 830.6316 (expodability), 830.6319 (miscibility), 830.6321 (dielectric breakdown voltage), 830.7100 (viscosity), 830.7220 (boiling point), and 830.7520 (particle size) are acceptable.
4. The product chemistry data submitted & cited for the guidelines 830.6302 (color), 830.6303 (physical state), 830.6313 (stability at normal & elevated temperatures), 830.6314 (oxidation/reduction), 830.7000 (pH), 830.7050 (UV-VIS), 830.7200 (melting point), 830.7300 (density), 830.7370 (dissociation constant), 830.7550 ($K_{o/w}$), 830.7840 (water solubility), and 830.7950 (vapor pressure) are acceptable.
5. The registrant is required to submit the results of one year storage stability (830.6317) & corrosion characteristics studies (830.6320) for the proposed product. It is recommended that the observations should be made at 0, 3, 6, 9 and 12 months intervals..

BARCODE: D404382; FILE SYMBOL No.: 88783-G; PRODUCT: Technical Sulfentrazone

830.1550: Product identity & composition: (MRID No. 488907-01)

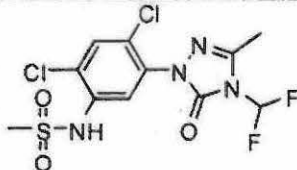
Test Item:	Sulfentrazone TGA1
Classification:	Herbicide
Active Ingredient:	Sulfentrazone
Empirical Formula:	C ₁₁ H ₁₀ Cl ₂ F ₂ N ₄ O ₃ S
Molecular Weight:	387.2
CAS Registry Number:	122836-35-5
IUPAC Name:	2',4'-dichloro-5'-(4-difluoromethyl-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl)methanesulfonanilide
Structure Formula:	

Table 1. Manufacturing and Impurity Data for Technical TGA1 "Technical Sulfentrazone."				
GLN	Requirement	MRID	Status	Details and/or Deficiency
830.1550	Product Identity & Composition	488907-01	A	The registrant has submitted a basic CSF (dated 7-12-12) with nominal concentration of 94% for the AI, which agrees with the product label claim nominal concentration.
830.1600	Description of materials used to produce the product	488907-01	A	The registrant has provided MSDS's for all the starting materials used in the production of sulfentrazone technical.
830.1620	Description of production process	488907-01	A	The sulfentrazone technical is produced in [REDACTED]. Details of the each steps of the process have been submitted. The quality assurance steps taken have been provided.
830.1670	Discussion on the formation of impurities	488907-01	A	[REDACTED] impurities on the basic CSF as identified during the 5 batch analysis. The origin and mechanisms of their formations have been discussed. [REDACTED]
830.1700	Preliminary analysis	488907-02 488907-03	A	The AI and impurities have been identified in the 5 batches of technical sulfentrazone by HPLC/UV method with external standard quantification. The structures of the AI & the impurities have been confirmed by NMR, HPLC and HPLC-MS methods. The analytical methods have been validated for precision, linearity and accuracy.
830.1750	Certified limits	488907-01	A	The certified limits of AI and impurities are based on the five bath analysis.
830.1800	Enforcement analytical method	488907-02 488907-03	A	The validated analytical method used during the 5 batch analysis is applicable for enforcement purposes.
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

830 Series Subgroup B (Physical-Chemical Properties)
Table 2: Physical and Chemical Properties of: Technical TGA1 "Technical sulfentrazone"

GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	488907-04	A	Oyster White
830.6303	Physical state	488907-04	A	Solid(Powder)
830.6304	Odor	488907-04	A	Odorless
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	488907-04	A	Sulfentrazone was considered to be stable in terms of Al content when exposed to Fe, Al, Fe (II) acetate and aluminium acetate for 14 days at room temperature (25°C). Sulfentrazone was considered to be stable in terms of Al content when exposed to Fe, Al, Fe (II) acetate and aluminium acetate for 14 days at 54°C.
830.6314	Oxidation/reduction: chemical incompatibility	488907-04	A	The test item did not react vehemently with Fe powder, water, monoammonium phosphate, kerosene, and is not compatible with 0.1M KMnO ₄ .
830.6315	Flammability	488907-05	A	Waiver request
830.6316	Explosibility	488907-05	A	Waiver request
830.6317	Storage stability	488907-04 488907-05	U	Stable at 54°C for two weeks. One year study required.
830.6319	Miscibility	488907-05	A	Waiver request
830.6320	Corrosion characteristics	488907-05	N	Waiver request denied. One year study required.
830.7000	pH	488907-04	A	4.21 at room temperature
830.7050	UV/Visible absorption	488907-04	A	See the results given in the table below
830.7100	Viscosity	488907-05	A	Waiver request
830.7200	Melting point	488907-04	A	120.9 – 121.9°C
830.7220	Boiling point	488907-05	A	Waiver request
830.7300	Density	488907-04	A	1.320 g/mL 20°C
830.7370	Dissociation constants in water (DC)	488907-04	A	pK _a = 6.64
830.7550	Partition coefficient	488907-04	A	Log P _{o/w} = 1.62
830.7840	Water solubility	488907-04	A	See the results below
830.7950	Vapor pressure	488907-05	A	1.3 x 10 ⁻⁴ mPa at 25°C (cited from literature)

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ;
U = Up-grade (additional information required); W = waivers

830.7050: UV/VIS results for sulfentrazone technical

UV-Vis	pH 5.18	$\log \epsilon$ (208 nm)= 4.59
		$\log \epsilon$ (290 nm)= 3.08
	pH 1.10	$\log \epsilon$ (287 nm)= 3.08
		$\log \epsilon$ (429 nm)= 2.19
		$\log \epsilon$ (491 nm)= 2.11
	pH 12.69	$\log \epsilon$ (261 nm)= 4.24
		$\log \epsilon$ (307 nm)= 3.51
		$\log \epsilon$ (489 nm)= 2.36

830.7840: Solubility in water & organic solvents

Solubility	20 ± 0.5 °C	pH 5 buffer solution	333.6 mg/L
		pH 7 buffer solution	918.1 mg/L
		pH 9 buffer solution	30.1 g/L
		methanol	65.8 g/L
		n-octanol	3.51 g/L
		n-hexane	50.14 mg/L

830.1800: (enforcement analytical method) (MRID No. 488907-02 & 488907-03)

The analytical method described under the guideline 830.1700 (preliminary analysis) can be used for enforcement analytical purposes.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Office of Pesticide Programs
Registration Division (7505 P)

08/JAN/2013

Similarity Determination

MEMORANDUM

Name of Product: Technical Sulfentrazone
EPA File Symbol: 88783-G
DP Barcode: 404385
Decision No.: 467536
Action Code: R310
PC Codes: 129081

From: Masih Hashim, Team Leader-Toxicology
Technical Review Branch
Registration Division (7505P)

MH
Bryan T. Bach
Jan-9-2013

To: Bethany Benbow, RM Team 23
Herbicide Branch
Registration Division (7505P)

Applicant: Summit Agro USA, LLC
Cary, NC 27518


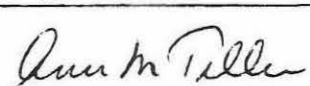
FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Sulfentrazone	94.0
<u>Inert Ingredient(s):</u>	<u>6.0</u>
	Total: 100.0

ACTION REQUESTED: The Registrant requests the cite-all method for a similarity action. The cited product is #279-3149 and the proposed product is #88783-G.

RECOMMENDATIONS: TRB has approved the cite-all method for a similarity action for this product, #88783-G.

The proposed label indicates the Signal Word Caution consistent with the cited product, having precautionary statements for oral, dermal, inhalation and eye toxicity of Toxicity Category III.

 United States Environmental Protection Agency Washington, DC 20480		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number Summit Agro USA, LLC/88783-		2. EPA Product Manager K. Montague	
4. Company/Product (Name) Summit Agro USA, LLC/Technical Sulfentrazone		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Summit Agro USA, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>279-3149</u> Product Name <u>Sulfentrazone Technical</u>	
Section - II			
<input type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input checked="" type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) This application falls under PRIA Category R310 (46: New product) because it is an application for registration of new manufacturing use product which is substantially similar to a currently registered product. The fee has been paid (\$4,807) and the decision timeline is 6 months.			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>PE lined fiberboard drums</u>
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55 lb/22 kg	
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled <input type="checkbox"/> Other _____	
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Ann M. Tillman		Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Ann M. Tillman		5. Date 7/17/12	

PYXIS REGULATORY CONSULTING, INC.

48890700

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

July 17, 2012

COURIER DELIVERY

Kathryn Montague (PM 23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Summit Agro USA, LLC
Technical Sulfentrazone (EPA File Symbol 88783-)
Application for New Pesticide Registration
PRIA Category R310

Dear Ms. Montague,

On behalf of Summit Agro USA, LLC, we are submitting an application for registration of Technical Sulfentrazone (EPA File Symbol 88783-), a manufacturing use product containing the active ingredient sulfentrazone. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Three (3) Copies of the Proposed Labeling
4. A CD containing an electronic version of the label
5. Certification with Respect to Label Integrity
6. Agency Internal Use Copy of the Data Matrix
7. Public File Copy of the Data Matrix
8. Certification with Respect to Citation of Data (EPA Form 8570-34)
9. Copy of the PRIA payment
10. Letter of Authorization
11. Product Specific Data (3 copies each):

48890701	Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for Technical Sulfentrazone. <i>Contains Confidential Business Information.</i>
48890702	Volume 2	830.1700, 830.1800	Li, H. Preliminary Analysis and Enforcement Analytical Method of Sulfentrazone TGA1. Validation of Analytical Methodology for the Assay of Related Significant Impurities and Subsequent 5-Batch Analysis of Sulfentrazone TGA1. <i>Contains Confidential Business Information.</i>

48890703	Volume 3	830.1800	Li, H. Validation of Analytical Methodology for the Assay of Active Ingredient in Sulfentrazone TGAI.
48890704	Volume 4	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7570, 830.7840	Li, H. Chemical and Physical Characterization of Sulfentrazone TGAI: Color, Physical State, Odor, Stability, Oxidation/Reduction, pH, UV-Vis, Melting Point, Density, Dissociation Constant, Partition Coefficient and Solubility.
48890705	Volume 5	830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7100, 830.7220, 830.7520, 830.7950	Tillman, A. M. Technical Sulfentrazone: Waiver Request for Physical and Chemical Properties.

Summit Agro USA, LLC is using the cite-all method of support. As per EPA's interpretations of 40 CFR Parts 152.86(b)(2)(i) and 152.93(b)(2)(i), Summit Agro USA, LLC submitted notices of intent to apply and offers to pay to all companies on the March 29, 2012 Data Submitter's List. This action falls under Category R310 (46: New manufacturing use product). The fee due which has been paid is \$4,807.

We trust you will find this application complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone at (253) 853-7369 if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

cc: K. Branly,
Consultant for Summit Agro USA, LLC



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 2, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-467536
EPA File Symbol or Registration Number: 88783-G
Product Name: TECHNICAL SLFENTRAZONE
EPA Receipt Date: 20-Jul-2012
EPA Company Number: 88783
Company Name: SUMMIT AGRO USA, LLC

ANN M. TILLMAN
PYXIS REGULATORY CONSULTING, INC
SUMMIT AGRO USA, LLC
4110 136TH ST. NW
GIG HARBOR, WA 98332-

SUBJECT: Reclassification of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has reclassified your application that is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act. The action has been reclassified from action code R300 to action code R310:

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

The fee for action code R310 is \$4,807. The fee has been paid in full and no refund will be forthcoming due to the reclassification.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m. zha".

Front End Processing Staff
Information Technology & Resources Management Division

Emma Becker

From: Ann Tillman
Sent: Monday, July 16, 2012 1:29 PM
To: PRC-Admin
Subject: FW: Pay.gov Payment Confirmation: PRIA Service Fees

-----Original Message-----

From: paygovadmin@mail.doc.twai.gov [<mailto:paygovadmin@mail.doc.twai.gov>]
Sent: Monday, July 16, 2012 4:27 PM
To: Ann Tillman
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 257BKBRD
Agency Tracking ID: 74335267329
Transaction Type: Sale
Transaction Date: Jul 16, 2012 4:26:50 PM

Account Holder Name: Susan Hill
Transaction Amount: \$4,807.00
Billing Address: 8000 Regency Park
Billing Address 2: Suite 265
City: Cary
State/Province: NC
Zip/Postal Code: 27518
Country: USA
Card Type: Visa
Card Number: *****4824

Decision Number:
Registration Number:
Company Name: Summit Agro USA LLC
Company Number: 88783
Action Code: R310

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 23, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-467536
EPA File Symbol or Registration Number: 88783-G
Product Name: TECHNICAL SLFENTRAZONE
EPA Receipt Date: 20-Jul-2012
EPA Company Number: 88783
Company Name: SUMMIT AGRO USA, LLC

ANN M. TILLMAN
PYXIS REGULATORY CONSULTING, INC
SUMMIT AGRO USA, LLC
4110 136TH ST. NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The action has been identified as action code R300:

NEW PRODUCT;ME-TOO PRODUCT FAST TRACK;

The fee for action code R300 is \$1,434. Payment in the amount of \$4,807 was submitted for this action. A refund in the amount of \$3,373 will be sent to you when this action is completed unless the action code is reclassified.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "M. J. [unclear]", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 27, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PYXIS REGULATORY CONSULTING, INC
SUMMIT AGRO USA, LLC
4110 136TH ST. NW
GIG HARBOR, WA 98332

Report of Analysis for Compliance with PR Notice 11-3

Thank you for your submittal of 20-JUL-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-3. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Summit Agro USA, LLC c/o Pyxis Reg. Consulting 4110 136th St. NW Gig Harbor, WA 98332	EPA Registration Number/File Symbol 88783-
Active Ingredient(s) and/or representative test compound(s) sulfentrazone	Date 7/17/12
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) TGA1	Product Name Technical Sulfentrazone

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Ann M. Tillman

Date

7/17/12

Typed or Printed Name and Title

Ann M. Tillman, Agent


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date July 17, 2012			EPA Reg. No./File Symbol 88783-		Page 1 of 4
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518			Product Technical Sulfentrazone		
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	Volume 1	Summit Agro USA, LLC	OWN	
830.1600	Description of Materials Used to Produce the Product	Volume 1	Summit Agro USA, LLC	OWN	
830.1620	Description of Production Process	Volume 1	Summit Agro USA, LLC	OWN	
830.1650	Description of Formulation Process				Not required ¹
830.1670	Discussion of Formation of Impurities	Volume 1	Summit Agro USA, LLC	OWN	
830.1700	Preliminary Analysis	Volume 2	Summit Agro USA, LLC	OWN	
830.1750	Certified Limits	Volume 1	Summit Agro USA, LLC	OWN	
830.1800	Enforcement Analytical Method	Volume 2 Volume 3	Summit Agro USA, LLC Summit Agro USA, LLC	OWN OWN	
830.6302	Color	Volume 4	Summit Agro USA, LLC	OWN	
830.6303	Physical State	Volume 4	Summit Agro USA, LLC	OWN	
830.6304	Odor	Volume 4	Summit Agro USA, LLC	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Volume 4	Summit Agro USA, LLC	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility	Volume 4	Summit Agro USA, LLC	OWN	
830.6315	Flammability	Volume 5	Summit Agro USA, LLC	OWN	Waiver ²
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 17, 2012

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DATA MATRIX


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Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518			Product Technical Sulfentrazone		
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explosibility	Volume 5	Summit Agro USA, LLC	OWN	Waiver ³
830.6317	Storage Stability	Volume 5	Summit Agro USA, LLC	OWN	PRN 92-5 ⁴
830.6319	Miscibility				Not required ⁵
830.6320	Corrosion Characteristics	Volume 5	Summit Agro USA, LLC	OWN	PRN 92-5 ⁴
830.6321	Dielectric Breakdown Voltage				Not required ⁶
830.7000	pH	Volume 4	Summit Agro USA, LLC	OWN	
830.7050	UV/Visible Absorption	Volume 4	Summit Agro USA, LLC	OWN	
830.7100	Viscosity				Not required ⁷
830.7200	Melting Point/Melting Range	Volume 4	Summit Agro USA, LLC	OWN	
830.7220	Boiling Point/Boiling Range				Not required ⁸
830.7300	Density/Relative Density/Bulk Density	Volume 4	Summit Agro USA, LLC	OWN	
830.7370	Dissociation Constants in Water	Volume 4	Summit Agro USA, LLC	OWN	
830.7520	Particle size, fiber length, diameter distribution	Volume 5	Summit Agro USA, LLC	OWN	Waiver ⁹
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				See 830.7570
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7570
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 17, 2012

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DATA MATRIX

Date July 17, 2012			EPA Reg. No./File Symbol 88783-		Page 3 of 4
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518			Product Technical Sulfentrazone		
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography	Volume 4	Summit Agro USA, LLC	OWN	
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	Volume 4	Summit Agro USA, LLC	OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	Volume 4	Summit Agro USA, LLC	PL	
870.1100 (81-1)	Acute Oral Toxicity: Rat	Cite-All	Summit Agro USA, LLC	PAY	
870.1200 (81-2)	Acute Dermal Toxicity: Rat	Cite-All	Summit Agro USA, LLC	PAY	
870.1300 (81-3)	Acute Inhalation Toxicity: Rat	Cite-All	Summit Agro USA, LLC	PAY	
870.2400 (81-4)	Primary Eye Irritation: Rabbit	Cite-All	Summit Agro USA, LLC	PAY	
870.2500 (81-5)	Primary Dermal Irritation	Cite-All	Summit Agro USA, LLC	PAY	
870.2600 (81-6)	Dermal Sensitization	Cite-All	Summit Agro USA, LLC	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 17, 2012


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DATA MATRIX

Date July 17, 2012		EPA Reg. No./File Symbol 88783-		Page 4 of 4	
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific and Generic Data Requirements					
Summit Agro USA, LLC is using the cite-all option to satisfy product specific and generic data requirements. Summit Agro USA, LLC will make offers-to-pay to the following companies on the March 29, 2012 Data Submitters List for sulfentrazone.					
		Cite-All	FMC Corp. Agricultural Products Group	PAY	
		Cite-All	E. I. DuPont de Nemours and Co., Inc.	PAY	
		Cite-All	PBI/Gordon Corp.	PAY	
		Cite-All	Chemsico	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	FIFRA Endangered Species Task Force LLC	PAY	
		Cite-All	Agricultural Handlers Exposure Task Force	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 17, 2012

Endnotes for Data Matrix for Technical Sulfentrazone

-
- ¹ **830.1650** - These data are not required for the registration of a manufacturing use product. See 830.1620 for production process information.
- ² **830.6315** - Summit Agro USA, LLC requests a waiver from this data requirement because Technical Sulfentrazone is a solid and is not expected to be flammable.
- ³ **830.6316** - Summit Agro USA, LLC requests a waiver from this data requirement because sulfentrazone does not have the chemical bonds or functional groups associated with explosive chemicals.
- ⁴ **830.6317, 830.6320** - Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Summit Agro USA, LLC will conduct these studies if requested by the Agency.
- ⁵ **830.6319** - This data requirement is required when the MUP is an emulsifiable liquid and to be diluted with petroleum solvents. Technical Sulfentrazone is a technical material that is a solid and is not to be diluted with petroleum solvents. This data requirement is not applicable to Technical Sulfentrazone.
- ⁶ **830.6321** - These data are not required unless the product is an end-use product. Technical Sulfentrazone is a technical grade material and this data requirement is not applicable.
- ⁷ **830.7100** - This requirement is not applicable to Technical Sulfentrazone because it is a solid.
- ⁸ **830.7220** - This requirement is not applicable to Technical Sulfentrazone because it is a solid. The melting point of Technical Sulfentrazone was determined and that data is presented Volume 3 of this submission.
- ⁹ **830.7520** - A waiver is requested by Summit Agro USA, LLC for this data requirement for Technical Sulfentrazone because it is not a fibrous material and is not a water-insoluble material.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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DATA MATRIX


Date July 17, 2012			EPA Reg. No./File Symbol 88783-		Page 1 of 4
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518			Product Technical Sulfentrazone		
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
					Not required ¹
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	Waiver ²
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 17, 2012

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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Date July 17, 2012		EPA Reg. No./File Symbol 88783-		Page 2 of 4	
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Summit Agro USA, LLC	OWN	Waiver ³
			Summit Agro USA, LLC	OWN	PRN 92-5 ⁴
					Not required ⁵
			Summit Agro USA, LLC	OWN	PRN 92-5 ⁴
					Not required ⁶
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
					Not required ⁷
			Summit Agro USA, LLC	OWN	
					Not required ⁸
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	Waiver ⁹
					See 830.7570
					See 830.7570
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 17, 2012

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATA MATRIX

Date July 17, 2012			EPA Reg. No./File Symbol 88783-		Page 3 of 4
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518			Product Technical Sulfentrazone		
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
					See 830.7840
			Summit Agro USA, LLC	PL	
			Summit Agro USA, LLC	PAY	
			Summit Agro USA, LLC	PAY	
			Summit Agro USA, LLC	PAY	
			Summit Agro USA, LLC	PAY	
			Summit Agro USA, LLC	PAY	
			Summit Agro USA, LLC	PAY	
			Summit Agro USA, LLC	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 17, 2012




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date July 17, 2012		EPA Reg. No./File Symbol 88783-		Page 4 of 4	
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					
			FMC Corp. Agricultural Products Group	PAY	
			E. I. DuPont de Nemours and Co., Inc.	PAY	
			PBI/Gordon Corp.	PAY	
			Chemsico	PAY	
			Spray Drift Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			FIFRA Endangered Species Task Force LLC	PAY	
			Agricultural Handlers Exposure Task Force	PAY	
			Signature 		Name and Title Ann M. Tillman, Consultant

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
088783-xxxxx	July 17, 2012	088783-xxxxx.20120717.Technical Sulfentrazone label.v1.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature
Ann M. Tillman
Agent, Summit Agro USA, LLC

July 17, 2012
Date

There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.

If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Renae Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423



8000 Regency Park Suite 265 Cary, North Carolina, 27519 919-653-4620

September 1, 2011

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agents for Summit Agro USA, LLC (EPA Company Number pending), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in cursive script that reads "Susan J. Hill".

Susan J Hill

Chief Financial Officer

Summit Agro USA, LLC

cc: Pyxis Regulatory Consulting, Inc.

R 300 and 301

100% identical (repack): YES or (NO) (circle one)

{If **yes**, it's a 100% repack - then product chemistry, acute toxicity and efficacy data are not required}

Data on Group A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition	✓	
830.1600	Description of materials used to produce the product	X	
830.1650	Description of formulation process	X	
830.1670	Discussion on the formation of impurities	X	
830.1700	Preliminary analysis	X	
830.1750	Certified limits (158.345)	X	
830.1800	Enforcement analytical method	X	

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color	X	
830.6303	Physical State	X	
830.6304	Odor	✓	
830.6314	Oxidation/Reduction (Chemical incompatibility)	X	
830.6315	Flammability	X	
830.6316	Explosibility	✓	
830.6317	Storage stability	X	
830.6319	Miscibility	X	
830.6320	Corrosion Characteristics	X	
830.6321	Dielectric Breakdown voltage	X	
830.7000	pH	X	
830.7100	Viscosity	X	
830.7300	Density	X	

Fee for Service

{920597L~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 23

Receipt No.

S-

920597

EPA File Symbol/Reg. No.

88783-G

Pin-Punch Date:

7/20/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R310

Granted: R300

Amount Due: \$ 1434

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: S. Hill

Date: 7/23/12

Remarks:

PM - Applicant notes that the pending product is substantially similar to another registered product.

Receipt for Section 3					
S:	920597	Resubmission:	<input type="radio"/> Yes <input checked="" type="radio"/> No		
Regulatory Type:	Product Registration - Section 3	Fee For Service:	<input checked="" type="radio"/> Yes <input type="radio"/> No		
Application Type:	New Registration	Billable:	<input checked="" type="radio"/> Yes <input type="radio"/> No		
Company:	88783 SUMMIT AGRO USA, LLC		V	<div>Print Letter</div> <div>Enter More Information</div> <div>Tracking</div>	
Risk Manager:	Registration Division, Risk Management Team 23				
Product #:	88783-G	Product Name:	TECHNICAL SLFENTRAZONE		
Override#:					
Me Too Section3:		Me Too Product Name:			
Application Date:	17-Jul-2012	OPP Rec'vd Date:	20-Jul-2012		
Front End Date:	20-Jul-2012	Risk Manager Send Date:			
FFS Due Date:		Negotiated Due Date:			
OPP Target Date:					
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>		
Receipt Description:				View/Edit	
NEW REGISTRATION				New Ingredient Request Date: <input type="text"/>	
				New Ingredient Received Date: <input type="text"/>	
Form A:	<input type="checkbox"/>	Signature Date:	<input type="text"/>	Form B:	<input type="checkbox"/>
		Signature Date:	<input type="text"/>		

Completion of 21-Day Content Screen


PM- 23

EPA Reg. # (File Symbol) 88783-G

Decision # D 467536

Data package delivered to
you on 7/31/12.
(date)

Jacket/Mini-jacket will be
transferred to you today.
(Pick up from Document Center)

Thank you, 

Registration Division's 21-Day Content Team

Memorandum

Date: 07/27/12

To: PM 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission

21-Day Screen Completed by
Contractor

21-Day Expires on 8-10-12

Jacket # 88783-G
MRID# 488907

Content Screen: Recommend to ☒ Pass/Fail

11-3 Review: ☒ Pass/Fail/NA

Overall Status: Recommend to ☒ Pass/Fail

Transfer This Jacket to:

STEPHEN SCHTAIBLE

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 7-20-12 ^{3/23/09}

Experts In-Processing Signature: B. R. Date 7-24-12 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>88783-G</u>		EPA Receipt Date: <u>7-20-12</u>								
Items for Review				Yes	No	N/A*				
✓ 1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X						
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X						
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) <u>No Inert / Impurities only</u>		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 50%; text-align: center;">yes</th> <th style="width: 50%; text-align: center;">no</th> </tr> <tr> <td style="text-align: center;">X</td> <td></td> </tr> </table>	yes	no	X				
yes	no									
X										
✓ 3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X						
	Certificate and data matrix consistent			X						
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 50%; text-align: center;">yes</th> <th style="width: 50%; text-align: center;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no									
	If applicable, is there a letter of Authorization for exclusive use only.									
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X				
✓ 5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X						
	a) Selective Method (Fee category experts use)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 50%; text-align: center;">yes</th> <th style="width: 50%; text-align: center;">no</th> </tr> <tr> <td style="text-align: center;">X</td> <td></td> </tr> </table>	yes	no	X				
yes	no									
X										
	b) Cite-All (Fee category experts use)									
	c) Applicant owns all data (Fee category experts use)									
✓ 6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available) link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X						

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:



Technical & Impurities only, no inerts to review

Sacket Pass
11-03 Pass

FG

TRID 488907

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

